

In re Application of: AKSELROD ET AL
Serial No.: 10/528,456
Filed: September 18, 2003
Office Action Mailing Date: February 24, 2009

Examiner: George C Manuel
Group Art Unit: 3762
Attorney Docket: 29429

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-95 and 107-342 are in this Application. Claims 127-342 have been withdrawn from consideration. Claims 96-106 have been cancelled. Claims 1-126 have been rejected under 35 U.S.C. § 103. Claims 1, 127 and 196 have been amended herewith. New claims 343-355 have been added.

35 U.S.C. § 103 Rejections - Verrier et al

Claims 1-20, 28-80 and 96-126 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,902,250 to Verrier *et al.* in view of U.S. Patent No. 5,265,617 to Verrier *et al.*

The Examiner states that the '250 patent discloses a method of determining sleep states of a patient comprising the steps of: monitoring heart rate variability of the patient; and dynamically determining the sleep state of the patient based on the heart rate variability. The Examiner further states that heart rate variability includes determining chest wall impedance of the patient, and that the '250 patent teaches monitoring a frequency of eyelid movements and determining the breathing pattern based also on the frequency. The Examiner refers to FIGS. 3 and 4 of the '250 patents stating that FIG. 3 illustrates typical low frequency/high frequency (LF/HF) heart rate variability ratios for awake and sleep states, and FIG. 4 illustrates a relationship between heart rate and eyelid movement frequency during sleep.

The Examiner states that the '617 patent teaches the amplitude of beat-to-beat alternation represents cardiac electrical instability, and that R-R intervals are analyzed to estimate magnitudes of high and low frequency components of heart rate variability. The Examiner further states that the '617 patent teaches that the high and low frequency components indicate parasympathetic and sympathetic activity, respectively, and that the amplitude of beat-to-beat alternation, and the high and low frequency components of heart rate variability are simultaneously analyzed to diagnose cardiac

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electrical instability. The Examiner additionally states that the '617 patent teaches traditional methods of quantifying heart rate variability have relied on power spectrum (Fourier) analysis, and concludes that one of ordinary skill in the art would have found it obvious to combine the teachings of the '250 patent and the '617 patent to analyze R-R intervals to estimate magnitudes of a high and low frequency components of heart rate variability for determining a slow-wave sleep period and a non-slow-wave-sleep period, and sleep apnea.

The Examiner rejections are respectfully traversed. Claim 1, 127 and 196 have been amended and claims 96-106 have been cancelled.

The following relates primarily to the independent claims. The dependent claims are patentable at least by virtue of their dependency on their parent claims. While the dependent claims are not separately argued in order to simplify the response, applicants submit that at least some of the dependent claims add patentable subject matter.

It is firstly noted that the '250 and '617 patents share the primary inventor, and that the '250 patent incorporates the '617 patent by reference (see column 9 lines 16, 17 and 20), indicating that the contents of the '617 patent was known and understood by its entirety to the inventors of the '250 patent. Yet, in spite of this knowledge and understanding, the inventors of the sleep monitoring method of the '250 patent did not employ or even contemplate the combination suggested by the Examiner.

It is submitted that the '250 patent only teaches how to use the teachings of the '617 patent for the analysis of cardiac electrical instability with or without simultaneous analysis of autonomic nervous system regulation, but fails to disclose the use of the '617 patent for analyzing R-R intervals to estimate magnitudes of a high and low frequency components of heart rate variability for determining a slow-wave sleep and non-slow-wave-sleep periods, and/or sleep apnea.

Additionally, it is submitted that the '617 patent does not provide what the '250 patent lacks, as would be appreciated by the Examiner once the following arguments are considered.

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Claim 1 is directed to a method of determining an SWS period and a NSWS period. Although the terminology in the '250 patent includes the term "SWS", the teachings of the '250 patent does not include determining SWS and NSWS as claimed, at least from the following reason.

The '250 patent adopts a binary definition for the sleep states wherein a sleeping subject can be either in a REM state or a non-REM state (the '250 patent also refers to quiet wakefulness, which is not a sleep state). The '250 patent refers to the non-REM state as SWS (see, *e.g.*, column 1 lines 24-26). It is submitted that the skilled person would understand this binary definition as indicating that any non-REM (NREM) sleep epoch is SWS and, complementarily, any NSWS epoch is REM sleep period.

The present inventors use a different definition of the sleep states, according to which not any NREM epoch corresponds to SWS. This is in sharp distinction from the '250 patent which defines SWS and NREM as synonyms.

Claim 1 as presently amended explicitly claim that NSWS period encompass at least one REM sleep period and at least one NREM sleep period.

The amendment of claim 1 finds support throughout the specification as filed. For example, claim 35 (further discussed below) defines that (i) REM sleep is determined from a portion of the signals which corresponds to the NSWS period, indicating that NSWS includes REM sleep; and (ii) there is at least one NSWS period (referred to as a light sleep period) which is not REM, indicating that the NSWS also includes non-REM sleep.

Applicant submits that the amendment to claim 1 is not substantive and that it does no more then to make explicit the accurate definition of SWS and NSWS which was already implicitly part of claim 1.

It is submitted that the '250 and '617 patents do not render claim 1 obvious, at least because the NSWS of the '250 patent does not include NREM sleep period.

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Claim 28 is directed to a method of determining REM sleep and NREM sleep. the claim explicitly requires the use of a Poincare plot of a series of cardiac R-R intervals for determining the REM sleep and the NREM sleep.

However, none of the '250 and '617 patents even hints at such procedure. It is therefore submitted that the Examiner has not established a *prima facie* case of obviousness regarding claim 28.

Claim 35 includes all the limitations of claim 1. Claim 35 also includes the limitation that the method determines at least one sleep-onset (SO) period and a plurality of non-sleep periods. Claim 35 further includes the limitations that the method determines at least one REM period and obtains at least one light-sleep (LS) period defined as a NSWS period other than the SO period(s), other than the non-sleep periods and other than the REM period(s).

It is submitted that claim 35 is patentable at least from the reasons provided hereinabove with respect to claim 1. It is further submitted that claim 35 is patentable at least because none of the '250 and '617 patents teaches determining at least one SO period. It is additionally submitted that claim 35 is patentable at least because none of the '250 and '617 patents teaches LS period defined as a NSWS period other than the SO period(s), other than the non-sleep periods and other than the REM period(s).

There is therefore no *prima facie* case of obviousness regarding claim 35.

Claim 107 is directed to a method of determining sleep apnea. Claim 107 include the limitations of: (a) extracting a series of cardiac R-R intervals; (b) excluding intervals corresponding to awakening periods; (c) obtaining a power spectrum; and (d) using the power spectrum to determine the sleep apnea.

The '250 patent does teach any extraction of R-R intervals and certainly not excluding of cardiac R-R intervals that correspond to awakening periods and obtaining a power spectrum. It is noted that '250 patent diagnoses a respiratory disorder such as apnea from the frequency of eyelid movements and/or from the R-wave amplitude and pattern (see column 12 lines 25-27), but is silent with respect to the determination of apnea from a power spectrum obtained from a series of cardiac

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R-R intervals. It is emphasized, again, that although the R-R analysis of the '617 patent was known to the inventors of the '250 patent, they only contemplate using such analysis for analyzing provocation of cardiac electrical instability by autonomic nervous system activity and not for determining sleep apnea. It is therefore submitted that the '250 and '617 patents do not render claim 107 obvious, either singly or in combination.

For all the above reasons, Applicants respectfully request the Examiner withdraw the rejection of claims 1-20, 28-80 and 107-126.

35 U.S.C. § 103 Rejections - Geva et al

Claims 21-27 and 81-95 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Geva *et al*.

The Examiner states that Geva *et al*. disclose a method and system for processing and analyzing biomedical signals, such as ECG, EEG, EOG, EMG, oximetry and respiratory signals, and teach that body and electrode movements, rapid eye movements and eye blinks are temporal events that are detectable through differences from a contemporary ongoing EEG signal by using their energy, skewness, duration and fundamental frequency.

The Examiner holds that one of ordinary skill in the art would have found it obvious to obtain an R-wave duration function based on the teaching that in order to avoid wasting processing time on signals that do not resemble heartbeats, a first classification process is employed on the current Beat Under Test.

The Examiner's rejection is respectfully traversed.

Claim 21 is directed to a method of determining REM sleep and NREM sleep. A plurality of EMG parameters which are extracted from signals recorded from the chest, are used for determine at least one REM period.

Geva *et al*. show initial identification of signals having a heartbeat-like waveform, and teach that in order to avoid wasting processing time on signals that do not resemble heartbeats, a first classification process is employed on the current Beat

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Under Test (Geva *et al.*, paragraph 236, FIG. 2). Based on this teaching, the Examiner states that one of ordinary skill in the art would have found it obvious to obtain an R-wave duration function. The Examiner, however, does not provide a rationale which supports a conclusion of obviousness to use EMG parameters for determining REM period.

It is submitted that Geva *et al.* do not teach the detection of REM sleep from EMG parameters. Moreover, Geva *et al.* teach that REM sleep can be determined only from EOG signal (see paragraph 305 of Geva *et al.*). Thus, to this effect Geva *et al.* teach away from claim 21.

There is therefore no *prima facie* case of obviousness regarding claim 21.

Claim 81 is directed to a method of determining a body position or a change in the body position from signals of electrical activity recorded of a chest of a sleeping subject. R-wave duration function is used to determine the body position or the change in the body position of the sleeping subject.

Geva *et al.* teach the use of movement detectors for identifying time periods during which segments of raw data streams are associated with patient movements (paragraph 22). Geva *et al.* also teach a manipulation which allows the R-peak to be the most perceptible point in the heartbeat so as to eliminate the risk of misdetection of R-peaks due to noises, movements, T waves and other types of interference (paragraph 108). Geva *et al.* further teach detection of movements based on a change in the variance of the base line in the environment of a heartbeat that is suspected as pathological (FIG. 13 and paragraph 261).

However, Geva *et al.* are silent with respect to any relation between the R-wave duration function and the body position. In fact, Geva *et al.* do not refer R-wave duration at all. It is submitted that the skilled person would not confuse Geva's reference to the amplitude or magnitude of the R-wave with the R-wave duration of claim 81, since an amplitude and duration are orthogonal quantities.

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It is therefore submitted that Geva *et al.* do not render claim 81 obvious, since Geva *et al.* do not teach or imply use of R-wave duration function to determine body position or the change in body position.

For all the above reasons, Applicants respectfully request the Examiner withdraw the rejection of claims 21-27 and 81-95.

New Claims

New independent claim 343 includes limitations of original claims 1 and 28.

New dependent claims 344-355 include limitations found in original claims 29, 31, 36, 37, 3, 56, 58, 59, 66, 67, 70 and 79, respectively.

It is submitted that claim 343 is patentable at least because claims 1 and 28 are patentable, and claims 344-355 are patentable at least by virtue of their direct or indirect dependency on claim 343.

Rejoinder

It is noted that claims (127, 196), (142, 216), (149, 228), (156, 240), (282, 318), and (304, 329) include all the limitations of claims 1, 21, 28, 35, 81 and 107, respectively. A rejoinder of claims 127, 142, 149, 156, 196, 216, 228, 240, 282, 304, 318 and 329 and their dependent claims in accordance with 37 CFR 1.104 is respectfully requested once claims 1, 21, 28, 35, 81 and 107 are allowed.

In view of the above amendments and remarks it is respectfully submitted that the claims are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



Martin D. Moynihan
Registration No. 40,338

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Enclosures:

- Additional Claims Transmittal Fee